



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/308,192	07/14/99	BAXTER	A 229752000600

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HM22/0725

EXAMINER

LEE, L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

07/25/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/308,192**

Applicant(s)

**Baxter**

Examiner

**LI Lee**

Group Art Unit  
**1645**



☒ Responsive to communication(s) filed on Jun 29, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-22 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-22 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4 and 7-10, 20-21 drawn to a method for the treatment of autoimmune disease administering the cell wall of Mycobacterium or use of a cell wall component of Mycobacterium for the treatment of diabetes.

Group II, claim(s) 1, 5-10, , 20 and 22 drawn to a method for enhancing anti-tumor immune response administering the cell wall of Mycobacterium or use of a cell wall component of Mycobacterium for the treatment of carcinoma.

Group III, claim(s) 11-14, drawn to a method for preventing or delaying, curing or curing in association with onset of islet and/or pancreas transplant replacement administering the cell wall of Mycobacterium.

Group IV, claim(s) 11-14, drawn to a method for preventing or delaying, curing or curing in association with onset of ameliorating the effects of IDDM administering the cell wall of Mycobacterium.

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Group V, claim(s) 15-16, drawn to a composition comprising mycolyl-arabinogalactan-peptidoglycan (MAPG).

Group VI, claim(s) 17-19, drawn to a method for isolating components of MAPG.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VI appears to be that they relate to a cell wall component of Mycobacterium or a analogue.

However, Adam et al (US 4,152,423, May 1, 1979) teach a method of immunomodulatory therapy in a mammal administering a component of the cell wall of Mycobacterium (see column 16, claim 13).

Therefore, the technical feature linking the inventions of groups I-X does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a method for the treatment of autoimmune disease administering the cell wall of Mycobacterium.

The special technical feature of Group II is considered to be a method for enhancing anti-tumor immune response administering the cell wall of Mycobacterium.

The special technical feature of Group III is considered to be a method for preventing or delaying onset of islet and/or pancreas transplant replacement administering the cell wall of Mycobacterium.

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The special technical feature of Group IV is considered to be a method for preventing or delaying onset of ameliorating the effects of IDDM administering the cell wall of Mycobacterium.

The special technical feature of Group V is considered to be a composition comprising mycolyl-arabinogalactan-peptidoglycan (MAPG).

The special technical feature of Group VI is considered to be a method for isolating components of MAPG.

Since the special technical feature of each group is not present in the others, the unity is lacking. Accordingly, the claims which contain multiple inventions are subject to restriction under PCT Rule 13.1.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee  
July 24, 2000

  
PHUONG T. BUI  
PRIMARY EXAMINER